

REMARKS

Claims 1-3, 8-21, and 24-28 are presented for the Examiner's review and consideration. In this Response, Applicant has amended claim 1, 9, 21, and 24; and claim 28 has been added. Applicant believes that the claim amendments and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicant respectfully submits that they do not limit the range of any permissible equivalents. No new matter has been added.

35 U.S.C. § 112

Claims 1, 9, and 21 were rejected under 35 U.S.C. § 112 because the recited limitation "said anchor" had an insufficient antecedent basis for this limitation in the claim. Claims 1, 9, and 21 have been amended to provide an antecedent basis for this limitation.

35 U.S.C. § 103

Claims 1-3, 8-21, and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,099,552 to Adams ("Adams") in view of U.S. Patent No. 6,306,159 to Shwartz et al. ("Shwartz"); and claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Adams in view of Shwartz and further in view of U.S. Patent No. 4, 235,238 to Ogiu ("Ogiu"). For the reasons set forth below, Applicant respectfully submits that the rejected claims are patentable over Adams in view of Shwartz and Ogiu.

Adams in view of Shwartz

The rejection stated that Adams discloses the claimed device except for first and second suture sections being passed through and extend away from said first and second passages, respectively, the suture threaded through said first passage and second passage being operative to rotate said anchor when first suture section is tensioned and the second suture section is relaxed. The Examiner specifically stated that Shwartz teaches first and second suture sections (two

sections of 40) being passed through and extend away from said first 24 and second 26 passages, the suture threaded through said first passage and second passage being operative to rotate said anchor when first suture section is tensioned and the second suture section is relaxed. (Figs. 4-7).

Referring to Figures 4-7 of Shwartz, an outer wall anchor 20, inner mensical anchor 30, and suture 40 is shown, where the suture passes though first hole 24 and loops through second hole 26. As shown in the Figures, the holes 24 and 26 are located near the middle of the outer wall anchor 20. The suture 40 connects the outer wall anchor 20 and inner mensical anchor 30. As the suture 40 is tightened, the outer wall anchor 20 acts as a pulley to bring the two anchors together and to close a defect in the tissue. (Col. 4, lns. 8-13).

Figures 14-16 and col. 6, lns. 18-51 of Shwartz illustrate the method for inserting the device. The outer wall anchor 20 is located on a needle 80, and the needle 80 is inserted through the meniscus/tissue. (Col 6, lns. 20-21). A push rod 86 is used to deploy the outer wall anchor 20 outside of the tissue. (Col. 6, lns. 28-30). The outer wall anchor will then “flip” into position, thereby disallowing the device to pull back through the tissue. (Id.) *“This “flipping” is provided by locating first and second suture holes 24, 26 near the middle of outer wall anchor 20, or by providing hole 24b at or near the middle of outer wall anchor 20.”* (Id.) Only after the outer wall anchor 20 is deployed and the “flipping” has already occurred is the tension applied to the suture to provide support against the outer rim wall 16 of the tissue. (Id.)

As such, Shwartz discloses a device for repairing a defect in a tissue having an outer wall anchor with both first and second suture holes located *near the middle* of the outer wall anchor. An alternate embodiment has one hole that is also located near the middle of the outer wall anchor. “Flipping” of the anchor occurs by locating the holes near the middle and using a push rod to deploy the anchor outside of the tissue. After the “flipping” of the anchor, the anchor acts as a pulley by applying tension to the suture. Thus, Shwartz does not disclose an implant having suture passages located proximate a leading end portion of the anchor. Further, rotation of the anchor occurs by pushing the anchor with a push rod to its position outside of the tissue and not by tensioning the suture.

In contrast, the present invention discloses an implant for securing a suture relative to a body tissue having a first passage located proximate the pointed end portion of the implant and a first suture section threaded through the first passage. A force is applied at the first passage when the first suture section is tensioned, and the force applied by the tensioning of the suture section operates to rotate the implant.

Referring to Figures 7 and 8 of Applicant's invention, an anchor 158 is connected with a retainer 160 by a suture 162. (Figure 7, ¶0095 of Published App.). The anchor has a pointed end portion 176 and a pair of passages 168 and 172. (Figure 7). The first passage 168 is formed proximate the pointed end portion 176. The suture 162 has a first section 166 threaded through a first passage 168 and a second section 170 threaded through a second passage 172. (¶0096). Once the anchor is positioned relative to a layer of body tissue 152, a force 180 is applied against a trailing end of the anchor. (¶0098). As the anchor 158 moves into the body tissue under the influence of the force 180, the anchor moves through the layers 150 and 152 of body tissue. (¶0102). After moving through the layers, the first suture section 166 is tensioned. (Id.) The tensioning of the first suture section 166 applies a force at the first passage 168 that is effective to rotate the anchor 158 from the entrance orientation illustrated in Fig. 7 to the anchoring orientation illustrated in Fig. 8. (Id.)

Locating the first passage proximate the pointed end portion of the anchor and applying tension to the suture section threaded through the first passage is advantageous as compared to locating the passages in the middle of the anchor as taught in Schwartz. Applying the tension proximate the pointed end portion allows for easier movement as the anchor moves from the entrance orientation to the anchoring orientation and it enables rotation of the anchor without the need of a separate tool or push rod directing the movement of the anchor. The anchor acts as a lever and tension in the first suture section applies torque to the anchor to rotate the anchor about the location where the anchor moves through the tissue layers. After moving through the tissue layers, the anchor's trailing end becomes the anchor's pivot point. Because the anchor acts as a lever, the work needed to lift the anchor equals the force applied times the distance from the pivot point/trailing end. Therefore, the principle of mechanical advantage applies, which means

that by increasing the distance from the point of rotation, less tensioning force is needed to rotate the anchor. However, if the distance from the pivot point was maximized by locating the first passage at the tip of the anchor, the anchor would move back through the tissue layers when the first suture section is tensioned. By placing the first passage a necessary distance from the pointed end portion, this problem is solved.

Claim 1 recites, *inter alia*, an implant for securing a suture relative to a body tissue having a body portion with a pointed end portion, a first passage formed proximate the pointed end portion, and a suture threaded through the first passage. A force is applied at the first passage when the suture is tensioned, whereby the force operates to rotate the implant.

With respect to claim 1, Schwartz, as described above, teaches away from the claimed invention by locating the hole “near the middle” of its outer wall anchor. The “flipping” of the anchor is taught to be predicated on this fact. Also, flipping of the anchor occurs by pushing the anchor with a push rod to its position outside of the tissue and not by tensioning the suture. The only purpose taught by Schwartz of the suture being tensioned is to provide support against the outer wall of the tissue after the anchor has already been flipped. Thus, the Schwartz embodiment does not take advantage of the advantageous mechanical properties discussed above that occur by placing the passage near the leading end of the anchor as in Applicant’s invention.

Accordingly, Applicant respectfully submits that claim 1 is patentable over Adams in view of Schwartz. As claims 2, 3, 8, and 27 depend from claim 1, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependant claims are allowable over Adams in view of Schwartz for the same reasons.

Claim 9 recites, *inter alia*, an implant securing a suture relative to a body tissue as described above with respect to claim 1 but also including a second passage extending through the body portion, with the second passage located proximate the middle of the cylindrical body portion. First and second suture sections are passed through and extend away from the first and second passages, respectfully. The implant is then rotated when a force is applied at the first passage by tensioning the first suture section and the second suture section is relaxed.

With respect to claim 9, Shwartz, as described above, teaches away from the claimed invention by locating both its first and second suture holes near the middle of its outer wall anchor. Also, the flipping of the anchor is different as described above with respect to the arguments regarding claim 1. Furthermore, after the flipping has occurred in Shwartz, the entire suture is tensioned to provide support against the outer wall of the tissue. The two sections of the suture are in tension because it is operating as a pulley. Thus, the second suture section is not relaxed and the suture is not operating to rotate the implant.

Accordingly, Applicant respectfully submits that claim 9 is patentable over Adams in view of Shwartz. As claims 10-20 depend from claim 9, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependant claims are allowable over Adams in view of Shwartz for the same reasons.

Claim 21 recites, *inter alia*, an implant essentially the same as that of claim 9 except having a conical end instead of a pointed end and further specifies that the first passage is formed partially through the cylindrical body and partially through the pointed end portion. Accordingly, Applicant respectfully submits that claim 21 is patentable over Adams in view of Shwartz for at least the same reasons as discussed regarding claim 9. As claim 26 depends from claim 21, this dependent claim necessarily includes all the elements of its base claim. Accordingly, Applicant respectfully submits that this dependant claim is allowable over Adams in view of Shwartz for the same reasons.

Claims 24 and 25

Claims 24 and 25 were not discussed in the previous office action. Nevertheless, now recites an assembly, that includes, *inter alia*, a cylindrical body, a suture and a retainer, with the retainer having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture. Independent claim 24 is believed to be patentable over the cited art. As claims 25 and 28 depend from claim 24, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are

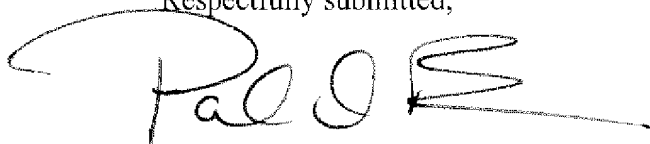
allowable.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee for a Request for Continued Examination (RCE) is believed to be due and is submitted herewith via credit card. However, please charge any other required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 782-A03-003-1).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul D. Bianco", with a long horizontal flourish extending to the right.

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